

**REMARKS**

This paper is filed in response to the final office action mailed on June 20, 2005. The Power of Attorney and Revocation of Prior Power of Attorney is forthcoming. The undersigned hereby verifies that he is authorized by the assignee of the present application to file this paper.

Claims 29-41 have been allowed. The remaining claims stand rejected; in response, claims 4 and 7 have been canceled and claims 1, 5-6, 8-12, 18-25, 42 and 43 have been amended; claims 1-3, 5-6 and 8-43 remain pending.

Applicants respectfully submit that this amendment is in full compliance with Rule 116 because it reduces the total number of pending claims and places all claims in a condition for allowance for the reasons set forth in the final office action on page 11, paragraph number 13. Specifically, each claim requires a distal end of the elongated member to include a tapered surface that receives a portion of the wall of the blood vessel that surrounds a puncture in the wall of the blood vessel which impedes entry of the elongated member into the blood vessel. No combination of the prior art teaches or suggests these features and therefore all pending claims are in a condition for allowance.

Turning to the rejections based upon the prior art, claims 1-5, 11 and 16-18 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,162,192 ("Cragg '192").

However, under MPEP § 2131,

"[t]o anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

*Citing, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Cragg '192 does not teach or suggest every element of amended claim 1 and therefore the anticipation rejection is improper. Specifically, Cragg '192 does not teach or suggest an elongated member with a distal end having a tapered surface that receives an edge of a blood vessel. The distal end 20 of Cragg in Fig. 1 and the remaining figures clearly shows a blunt, flat annular distal end with no tapered surface for catching an edge of a blood vessel. Thus, Cragg '192 cannot serve as an anticipating reference for amended claim 1 and therefore the anticipation rejection of claims 1-5, 11 and 16-18 is respectfully traversed.

Next, claim 6 is rejected under 35 U.S.C. § 103 as being unpatentable over Cragg '192. However, claim 6 merely recites that the lumen is off-center. Cragg '192 does not teach or suggest a distal end of an elongated member that includes a tapered surface for receiving an edge or portion of a blood vessel. Thus, Cragg '192 does not teach or suggest every element of independent claim 1 or dependent claim 6, and, under MPEP § 2142,

[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

*Citing, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also* MPEP § 2143-§ 2143.03 for decisions pertinent to each of these criteria.

Cragg '192 cannot serve as a base reference for an obviousness rejection of dependent claim 6 because it fails to teach or suggest every element of independent claim 1. Cragg '192 clearly does not teach or suggest a distal end of an elongated member that catches an edge or portion of a blood vessel surrounding a puncture of a blood vessel which impedes entry of the distal end of the elongated member from entering the blood vessel as recited in amended claim 1. Cragg '192 clearly does not even remotely suggest this feature. There is nothing to impede the distal end 20 of the Cragg '192 elongated member from entering the vessel other than the size of the vessel puncture. Accordingly, the obviousness rejection of claim 6 based upon Cragg '192 is traversed.

Next, the claims 7-10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cragg '192 in view of U.S. Patent No. 6,315,753 ("Cragg '753"). However, the combination of Cragg '192 and Cragg '753 still does not establish a *prima facie* case of obviousness. Specifically, Cragg '753 also fails to teach or suggest the distal end of an elongated member having a tapered surface for receiving a lip or edge of a blood vessel puncture. The Patent Office relies upon Fig. 26 of Cragg '753. However, element 164 is not an outer elongated member with a lumen as recited in amended claim 1 but instead is an inner member which describes Fig. 26 and member 164 as a pusher that is disposed within the

introduce 12 of Fig. 27. The element 164 of Fig. 26 pushes the sponge 140 in place and never engages an edge or lip surrounding a puncture of a blood vessel. Thus, Fig. 26 illustrates a pusher used with the introducer 12 of Fig. 1 but only as an inner member and therefore does not teach or suggest an elongated member that has a lumen extending therethrough and which has a distal end with a tapered surface for receiving an edge surrounding a puncture of a blood vessel. The only tapered distal end disclosed in either Cragg '192 or Cragg '753 is a distal end of a pusher rod 164 which is used to move the sponge towards the puncture. This is nothing to do with the outer elongated member and therefore no combination of these two references teaches or suggests every element of amended claim 1 and no *prima facie* case of obviousness has been established. Further, there is no suggestion or motivation to modify either Cragg '192 or Cragg '753 in a manner that would be required to meet the limitations of amended claim 1 because neither of these references address impeding the distal end of the outer elongated member from entering the blood vessel. Neither of these references address this problem nor provide a solution to it in the form of a tapered surface that receives a lip defining the puncture site.

Accordingly, applicants respectfully submit that the obviousness rejection of claims 7-10 has been traversed.

Next, the office action rejects claim 12, 19, 20, 23 and 24 under 35 U.S.C. § 103 as being unpatentable over Cragg '192 in view of U.S. Patent No. 5,437,631 ("Janzen"). In response, applicants present the following remarks.

The deficiencies of Cragg '192 are discussed above. Janzen in no way teaches or suggests a distal end of an outer elongated member with a tapered surface for receiving a lip of a blood vessel. None of the distal ends of the Janzen outer member are tapered and none of the figures in Janzen teach or suggest the receiving of part of the blood vessel in any tapered surface of a Janzen structure. Accordingly, no combination of Cragg '192 and Janzen teaches or suggests every element of amended claim 1 and therefore the obviousness rejection of claims 12, 19, 20, 23 and 24 are respectfully traversed.

Next, the office action rejects claims 13-15 under 35 U.S.C. § 103 as being unpatentable over Cragg '192 in view of U.S. Patent No. 5,395,353 ("Scribner"). The deficiencies of Cragg '192 are discussed above. Scribner is only cited for the proposition that it teaches materials of certain hardnesses. Thus, Scribner does not teach or suggest an elongated member with a tapered distal end for receiving an edge of a vessel puncture and

neither does Cragg. Therefore, no hypothetical combination of these two references presents a *prima facie* case of obviousness with respect to claim 1 and therefore the obviousness rejection of dependent claims 13-15 is traversed.

Next, the office action rejects claim 21 under 35 U.S.C. § 103 as being unpatentable over Cragg '192, Janzen '631 and further in view of U.S. Patent No. 6,063,085 ("Tay"). However, Tay is merely cited for the proposition that it discloses a vent hole. No structure in Tay remotely resembles the distal end of the elongated member as recited in amended claim 1. Neither does Janzen nor Cragg '192 as set forth above. Accordingly, no hypothetical combination of Cragg '192, Janzen and Tay teaches or suggests every element of amended claim 1 and therefore the obviousness rejection of dependent claim 21 has been traversed.

Next, the office action rejects claims 22 under 35 U.S.C. § 103 as being unpatentable over Cragg '192, Janzen and further in view of U.S. Patent No. 5,645,566 ("Brenneman"). The deficiencies of Cragg '192 and Janzen are discussed above. The Patent Office relies upon Fig. 1B of Cragg '192 for the proposition that it discloses a tapered outer surface for the elongated member. However, this tapered outer surface is not designed to receive an edge of the blood vessel and therefore Brenneman cannot supplement the deficiencies of Cragg '192 and Janzen as set forth above. Accordingly, no hypothetical combination of Cragg '192, Janzen and Brenneman teaches or suggests every element of amended claim 1 and therefore the obviousness rejection of dependent claim 22 based upon these three references is respectfully traversed.

Next, the office action rejects claims 25, 27 and 28 under 35 U.S.C. § 103 as being unpatentable over Janzen in view of U.S. Patent No. 5,601,602 ("Fowler"). However, Fowler fails to teach or suggest any element of the distal end of the elongated member that it is intended to receive an edge of a punctured vessel. The Patent Office relies upon Figs. 7 and 8 of Fowler however, these figures clearly show the elongated member extending into the blood vessel. No portion of the outer elongated member is intended to receive the lip of the blood vessel to prevent the elongated member from entering the blood vessel. Further, no outer portion of the member 56 of Fowler has a tapered surface for receiving an edge of the blood vessel. The outwardly flared wings 64 of Fowler are only extended after entry into the vessel. Nothing in Fowler is designed to keep the outer structure 56 from entering the vessel 70. As noted above, no structure of Janzen accomplishes this result either. Therefore, no

combination of Janzen and Fowler teaches or suggests every element of amended independent claim 25 and therefore the obviousness rejections of claims 25, 27 and 28 are respectfully traversed.

Next, the office action rejects claim 26 under 35 U.S.C. § 103 as being unpatentable over Janzen, Fowler and further in view of Tay. This rejection is traversed as Tay also fails to teach or suggest the outer elongated member having a tapered distal end for receiving an edge of the blood vessel. No combination of Janzen, Fowler and Tay teaches or suggests the tapered distal end recited in amended claim 25 that impedes entry of the distal end of the elongated member into the vessel and therefore no combination of these three references renders dependent claim 26 obvious.

Finally, claims 42 and 43 are rejected under 35 U.S.C. § 103 as being unpatentable over Tay in view of Janzen. In response, independent claim 42 has been amended to require the tapered distal end feature recited in independent claims 1 and 25 and, for the reasons set forth above, no hypothetical combination of these two references teaches or suggests every element of independent claim 42 and therefore the obviousness rejection of claims 42 and 43 is respectfully traversed.

An early action indicating the allowability of claims 1-3, 5-6 and 8-43 is earnestly solicited.

If the examiner has any further questions regarding this application, he is invited to telephone the undersigned at the number listed below.

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Respectfully submitted,

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